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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Bonnie Hepburn

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EXAMINER

POLANSKY, GREGG

ART UNIT

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1614

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/783,871	Applicant(s) HEPBURN ET AL.	
	Examiner GREGG POLANSKY	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 November 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18, 19, 60-62, 64 and 66-70 is/are pending in the application.
- 4a) Of the above claim(s) 18 and 19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 60-62, 64 and 66-70 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/12/2010 & 2/16/2010</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Claims

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission filed on 11/23/2009 has been entered.
2. Applicants' response, filed 11/23/2009, to the Office Action mailed 7/28/2009 is acknowledged. Applicants canceled Claims 63 and 65, amended Claim 60, and presented arguments in response to the Office Action.
3. Applicants' Information Disclosure Statements, filed 1/12/2010 and 2/16/2010, are acknowledged and have been reviewed.
4. Claims 18, 19, 60-62, 64 and 66-70 are pending.
5. Claim 60-62, 64 and 66-70 are presently under consideration.
6. Applicants' arguments have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 60-62, 64 and 66-70 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the Specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. This is a **New Matter** rejection.

Claim 60 has been amended to recite administration of the composition of the claim “at least 30 minutes” prior to a meal. The claim previously recited administration of the composition of the claim “within about 60 minutes” prior to a meal. Applicants’ disclosure, as originally filed, does not provide support for this limitation. The disclosure provides support for administration within 30 minutes prior to a meal and for administration at with about 60 minutes prior to a meal. There is no disclosure for the full scope of the claim (i.e., administration greater than 60 minutes prior to a meal).

The proscription against the introduction of new matter in a patent application (35 U.S.C. 132 and 251) serves to prevent an applicant from adding information that goes beyond the subject matter originally filed. See *In re Rasmussen*, 650 F.2d 1212, 1214, 211 USPQ 323, 326 (CCPA 1981). See MPEP § 2163.06 through § 2163.07 for a more detailed discussion of the written description requirement and its relationship to new matter. The claims as filed in the original specification are part of the disclosure and,

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therefore, if an application as originally filed contains a claim disclosing material not found in the remainder of the specification, the applicant may amend the specification to include the claimed subject matter. *In re Benno*, 768 F.2d 1340, 226 USPQ 683 (Fed. Cir. 1985). Thus, the written description requirement prevents an applicant from claiming subject matter that was not adequately described in the specification as filed. New or amended claims which introduce elements or limitations which are not supported by the as-filed disclosure violate the written description requirement. See, e.g., *In re Lukach*, 442 F.2d 967, 169 USPQ 795 (CCPA 1971) (subgenus range was not supported by generic disclosure and specific example within the subgenus range); *In re Smith*, 458 F.2d 1389, 1395, 173 USPQ 679, 683 (CCPA 1972) (a subgenus is not necessarily described by a genus encompassing it and a species upon which it reads).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

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under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 60-62, 64 and 66-70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Phillips (U.S. Patent No. 6,489,346 B1), in view of Hatlebakk et al. (Alimentary Pharmacology and Therapeutics, 2000, Vol. 14, pages 1267-1272).

Phillips teaches a pharmaceutical composition comprising a non-enteric coated proton pump inhibitor, in an amount of approximately 5 mg to approximately 300 mg, and a least one buffering agent, in an amount of approximately 0.1 mEq to approximately 2.5 mEq per mg of proton pump inhibitor. See Abstract. Phillips teaches the composition can be formulated as a powder, tablet, suspension tablet, chewable tablet, capsule, effervescent powder, effervescent tablet, pellets and graduals and liquids. The buffering agent is utilized to protect the proton pump inhibitor against gastric acid degradation. See column 11 lines 13-32. Phillips teaches omeprazole/sodium bicarbonate formulations wherein omeprazole is present in the formulation in the amount of 5 mg, 10 mg, 20 mg, 40 mg, 60 mg, 80 mg and 100 mg. See column 39, claim 1 and column 41, claims 36-41. The reference further teaches the formulation buffering agent (i.e., sodium bicarbonate) is present in the amount of 400 mg to 4000 mg. See column 42, claim 59. The proton pump inhibitor can be an enantiomer, isomer, derivative, free base or salt of the parent compound. See column 42, claim 57. Phillips teaches the proton pump inhibitor can be micronized. See

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column 41, claim 49. The composition taught further comprises excipients, including flavoring agents, diluents, disintegrants, preservatives and lubricants. See column 44, claim 116. Furthermore, Phillips teaches methods of treating gastrointestinal conditions, including GERD, by administration of the proton pump inhibitor/buffer formulations described above (including omeprazole/sodium bicarbonate). See column 12, lines 39-49.

It is noted that *In re Best* (195 USPQ 430) and *In re Fitzgerald* (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter, which there is reason to believe inherently includes functions that are newly cited, or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to “prove that subject matter to be shown in the prior art does not possess the characteristic relied on” (205 USPQ 594, second column, first full paragraph). Phillips teaches proton pump inhibitor/buffering agent compositions that are identical to those recited by the instant invention (*supra*). Therefore, the pharmacokinetic and pharmacodynamic characteristics of the compositions taught by Phillips would be the same as those recited by the instant claims. There is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter is in fact inherent in the prior art reference. *Schering Corp. v. Geneva Pharm. Inc.*, 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003); see also *Toro Co. v. Deere & Co.*, 355 F.3d 1313, 1320, 69 USPQ2d 1584, 1590 (Fed. Cir. 2004) (“[T]he fact that a characteristic is a necessary feature or result of a prior-art embodiment (that is itself sufficiently described and enabled) is

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enough for inherent anticipation, even if that fact was unknown at the time of the prior invention"). Furthermore, the plasma C_{\max} and T_{\max} of omeprazole is also affected by the size of the dose, the age and weight of the patient, as well as natural variability between individuals with regard to such factors as drug absorption, metabolism, and elimination.

Phillips does not disclose *per se* the administration of the proton pump inhibitor compositions at least 60 minutes prior to a meal, as required by the instant claims.

Hatlebakk et al. teach the administration of the proton pump inhibitors, omeprazole and lansoprazole, prior to a meal, appears to provide better acid suppression. Hatlebakk et al. studied administration of omeprazole and lansoprazole at 15 minutes prior to a meal (breakfast) and several hours prior to a meal (lunch). Better control of gastric acid was observed when the drugs were administered 15 minutes prior to a meal than what was observed when the drugs were administered several hours prior to a meal. See page 1267, "SUMMARY". Hatlebakk et al. suggest that food "may decrease systemic bioavailability and delay peak plasma concentrations" of proton pump inhibitors. See page 1271, lines 21-25. However, Hatlebakk et al. disclose, "[o]ptimal antisecretory effect occurs when the proton pumps are activated as the parietal cell is maximally stimulated as it is after a meal. Therefore, intake of [proton pump inhibitors] in relation to meals may be important to optimize their effect and avoid therapeutic failure." See paragraph bridging pages 1267 and 1268.

Whereas, Hatlebakk et al. teach administration proton pump inhibitors at 15 minutes and several hours prior to a meal, and they teach the potential effect of food on

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the bioavailability and peak plasma concentration of the proton pump inhibitors, it would have been obvious to one of ordinary skill in the art at the time of the invention to investigate administration of proton pump inhibitors (e.g. omeprazole) at other time points prior to a meal to optimize the effect on gastric pH.

One skilled in the art of pharmaceutical formulation is provided with guidelines from Phillips, sufficient to prepare formulations comprising a proton pump inhibitor, such as omeprazole, in combination with a buffer, such as sodium bicarbonate, to treat patients suffering from GERD. The cited references teach or suggest each limitation of the present claims. It is not inventive to discover the optimum or workable ranges by routine experimentation when general conditions of a claim are disclosed in the prior art. See *In re Aller*, 220 F.2d 454, 456, 105 USPQ233,235 (CCPA 1955) and MPEP 2144.05(11). The determination of the optimum dosages, particle sizes, gastric fluid pH ranges, serum concentrations over time and drug release rates to employ or to seek with the presently claimed agents, would have been a matter well within the purview of one of ordinary skill in the art. Such determination would have been made in accordance with a variety of factors. These would have included such factors as the age, weight, sex, diet and medical condition of the patient, severity of the disease, the route of administration, pharmacological considerations, such as the activity, efficacy, pharmacokinetics and toxicology profiles of the particular compound employed, whether a drug delivery system is utilized and whether the compound is administered as part of a drug combination. Thus, in the absence of evidence to the contrary, the currently claimed specific dosage amounts, particle sizes, serum concentrations over time and

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drug release rates are not seen to be inconsistent with those that would have been determined by the skilled artisan.

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Phillips with those of Hatlebakk et al. Whereas, Hatlebakk et al. teach administration proton pump inhibitors only at 15 minutes and several hours prior to a meal, and they teach the potential effect of food on the bioavailability and peak plasma concentration of the proton pump inhibitors, it would have been obvious to one of ordinary skill in the art at the time of the invention to, by routine experimentation, investigate administration of proton pump inhibitors (e.g. omeprazole) at other time points prior to a meal to optimize the effect on gastric pH.

“[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235(CCPA 1955); see also Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382 (“The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages.”) Furthermore, even in the absence of the teachings of Hatlebakk et al., one of ordinary skill would have recognized the presence or absence of food in the stomach of a patient can have a significant impact on the absorption of a drug. It would have been obvious to investigate the bioavailability of any drug, including the proton pump inhibitor compositions taught by Phillips, in fasted and non-fasted patients, through no more than routine experimentation

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole is *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

12. Applicants argue “[o]ne of ordinary skill in the art upon reading [Hatlebakk et al.] would be led to conclude that compositions comprising proton pump inhibitors require an administration of close proximity in time with a meal, e.g., 15 minutes or less according to Hatlebakk et al. for the activation of parietal cells by the meal.” Further, Applicants argue, “Hatlebakk et al. teaches away from the administration of proton pump inhibitors at greater than 15 minutes prior to a meal and also teaches that the administration of the proton pump inhibitors is to be administered near or close prior to a mealtime for maximum efficacy.”

The Examiner respectfully disagrees. As discussed above, Hatlebakk et al. teach administration proton pump inhibitors at 15 minutes and several hours prior to a meal, and they teach the potential effect of food on the bioavailability and peak plasma concentration of the proton pump inhibitors. Thus, it would have been obvious to one of

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ordinary skill in the art at the time of the invention to investigate administration of proton pump inhibitors (e.g. omeprazole) at other time points prior to a meal to optimize the effect on gastric pH.

Applicants further argue, "the compositions comprising 'non-enteric coated' proton pump inhibitors as presently claimed and. in Phillips are significantly different than the enteric coated omeprazole in the 20 mg capsule from Astra-Zeneca and the enteric coated lansoprazole in the 30 mg capsule from TAP Pharmaceuticals used in Hatlebakk et al. Compositions comprising "non-enteric coated" proton pump inhibitors as presently claimed contain at least one buffering agent. Surprisingly, these buffering agents allow the present compositions to activate the parietal cells without the need for food thereby obtaining optimal gastric acid secretion, unlike the compositions described in Hatlebakk et al. that require food to activate the parietal cells. This allows the compositions described in the instant application to be administered at least 30 minutes or greater prior to meal. The result could in no way have been predicted by one of ordinary skill in the art given the references cited by the Examiner.

The Examiner respectfully disagrees. As discussed above, even in the absence of the teachings of Hatlebakk et al., one of ordinary skill would have recognized the presence or absence of food in the stomach of a patient can have a significant impact on the absorption of a drug. It would have been obvious to investigate the bioavailability of any drug, including the proton pump inhibitor compositions taught by Phillips, in fasted and non-fasted patients, through no more than routine experimentation.

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13. Claims 60-62, 64 and 66-70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Phillips (U.S. Patent Application Pub. No. 2003/0191159 A1).

Phillips teaches methods and compositions for treating gastric acid disorders, including *inter alia* GERD and heartburn, employing pharmaceutical compositions comprising an acid labile proton pump inhibitor and a buffering agent. See Abstract, and page 11, paragraph 100, and page 54, claim 122. Phillips teaches the composition can be formulated as a powder, tablet, suspension tablet, chewable tablet, capsule, effervescent powder, effervescent tablet, pellets and graduals and liquids. The buffering agent is utilized to protect the proton pump inhibitor against gastric acid degradation. See page 5, paragraph 37 and page 52, claim 37. Phillips teaches the proton pump inhibitors are present in the composition in amounts from 5 mg to 1000 mg and unit doses of 5 mg, 10 mg, 15 mg, 20 mg, 25 mg, 30 mg, 40 mg, 50 mg, 60 mg, 75 mg, 80 mg, or 100 mg. See page 10, paragraphs 84 and 85. The reference teaches the buffering agent present in the composition in an amount of 0.1 mEq to 2.5 mEq per mg of proton pump inhibiting agent. The reference further teaches the formulation buffering agent (i.e., sodium bicarbonate) is present in the amount of 250 mg to 4000 mg. See page 52, claim 26. The proton pump inhibitor can be in the form of a salt, ester, amide, enantiomer, isomer, tautomer, prodrug, and derivative. See page 7, paragraph 65. Phillips teaches the proton pump inhibitor can be micronized. See page 13, paragraph 131. The composition further comprises excipients, including flavoring agents, diluents, disintegrants, lubricants, preservatives and lubricants. See page 53, claim 70. The reference teaches the proton pump inhibitor can be enteric coated or

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uncoated. See page 5, paragraphs 37 and 38, and page 52, claim 45. The Phillips reference teaches that the composition buffering agent is present in an amount sufficient to increase gastric fluid pH of the stomach to a pH that inhibits acid degradation of the proton pump inhibitor agent in the gastric fluid, so as to allow absorption of the proton pump inhibiting agent and to provide a therapeutically effective serum concentration of the proton pump inhibitor of at least 150 ng/ml within 15 minutes after ingestion of the composition. See page 52, claim 37. Phillips teaches an omeprazole T_{\max} of less than 1.5 hours with a C_{\max} ranging from 763 ng/ml to 1460 ng/ml for an omeprazole/sodium bicarbonate composition. See page 30, paragraph 325 and Table 9. Phillips further teaches a plethora of additional pharmacokinetic and pharmacodynamic information on proton pump inhibitor/buffering agent compositions. One of skill in the art would recognize that the pharmacokinetic and pharmacodynamic characteristics of a composition are complex and depend upon *inter alia* the age, body weight, general health, and sex of the patient, the rate of excretion, the drug combination and formulation, the fasting state of the subject, and the route of administration.

As discussed *supra*, *In re Best* (195 USPQ 430) and *In re Fitzgerald* (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter, which there is reason to believe inherently includes functions that are newly cited, or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to “prove that subject matter to be shown in the prior art does not possess the characteristic relied on” (205 USPQ 594, second column, first full paragraph).

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Phillips teaches proton pump inhibitor/buffering agent compositions and methods that are identical to those recited by the instant invention. Therefore, the pharmacokinetic and pharmacodynamic characteristics of the compositions taught by Phillips would be the same as those recited by the instant claims.

Phillips discloses administration of the proton pump inhibitor to a fasting subject. See, for example, page 31, paragraph 332; page 40, paragraph 458; page 52, claim 43; and page 53, claim 81. Thus, Phillips teaches administration "at least 60 minutes prior to a meal" as required by instant Claim 60.

One skilled in the art of pharmaceutical formulation is provided with guidelines from Phillips, sufficient to prepare formulations comprising a proton pump inhibitor, such as omeprazole, in combination with a buffer, such as sodium bicarbonate, to treat patients suffering from GERD. The reference teaches or suggests each limitation of the present claims. It is not inventive to discover the optimum or workable ranges by routine experimentation when general conditions of a claim are disclosed in the prior art. See *In re Aller*, 220 F.2d 454, 456, 105 USPQ233,235 (CCPA 1955) and MPEP 2144.05(11). The determination of the optimum dosages, particle sizes, gastric fluid pH ranges, serum concentrations over time and drug release rates to employ or to seek with the presently claimed agents, would have been a matter well within the purview of one of ordinary skill in the art. Such determination would have been made in accordance with a variety of factors. These would have included such factors as the age, weight, sex, diet and medical condition of the patient, severity of the disease, the route of administration, pharmacological considerations, such as the activity, efficacy, pharmacokinetics and

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toxicology profiles of the particular compound employed, whether a drug delivery system is utilized and whether the compound is administered as part of a drug combination. Thus, in the absence of evidence to the contrary, the currently claimed specific dosage amounts, particle sizes, serum concentrations over time and drug release rates are not seen to be inconsistent with those that would have been determined by the skilled artisan.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole is *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

14. Claims 60-62, 64 and 66-70 are rejected.
15. No claims are allowed.
16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to GREGG POLANSKY whose telephone number is

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(571)272-9070. The examiner can normally be reached on Mon-Thur 9:30 A.M. - 7:00 P.M. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Gregg Polansky/
Examiner, Art Unit 1614

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614